



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3038]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0206. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Request for Samples and Protocols

OMB Control Number 0910-0206--Extension

This information collection supports Agency regulations. Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to distributing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: 21 CFR 660.6 (Antibody to Hepatitis B Surface Antigen); 21 CFR 660.36 (Reagent Red Blood Cells); and 21 CFR 660.46 (Hepatitis B Surface Antigen).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by CBER, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test

results are requested by CBER. After official release is no longer required, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information including, but not limited to, manufacturing records, certain test records, and identity test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to the CBER Director at the time of initial distribution of each lot.

Section 660.46(a) contains requirements as to the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) contains the requirements as to the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by CBER, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and therapeutic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 79 manufacturers submitted samples and protocols in fiscal year (FY) 2017, under the regulations cited previously in this document. FDA estimates that approximately 75 manufacturers submitted protocols under § 610.2 and 2 manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under §§ 660.36 or 660.46; however, FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2017 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the other protocols than under § 610.2.

In the *Federal Register* of May 11, 2018, (83 FR 22081), we published a notice soliciting public comment of the information collection. No comments were received.

We therefore estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
610.2--Requests for Samples and Protocols; Official Release	75	86.267	6,470	3	19,410
660.6(b)--Protocols	2	3.5	7	5	35
660.36(a)(2) and (b)--Samples and Protocols	1	1	1	6	6
660.46(b)--Protocols	1	1	1	5	5
Total					19,456

¹. There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 764 hours and a corresponding increase of 262 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: August 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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